

Notice of Allowability

Application No.

09/585,645

Examiner

Celine X Qian

Applicant(s)

ZOGHBI ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed on 1/23/04.
2. ☒ The allowed claim(s) is/are 40-46, 48, 112-114, 117-119 and 124.
3. ☒ The drawings filed on 03 September 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

Anne-Marie Falk
ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Applicant's representative Melissa Sistrunk on 2/6/04 and 2/20/04.

The application has been amended as follows:

Claim 40. A method of generating hair cells for an animal, comprising delivering directly to an inner ear of said animal a therapeutically effective amount of an atonal-associated nucleic acid sequence [to a cell of said animal], wherein hair cells develop in the ear of said animal and wherein said atonal-associated nucleic acid sequence encodes a polypeptide that has hair cell generating activity, has at least about 80% identity to SEQ ID NO:58, and comprises at least about 80% identity to SEQ ID NO:70, wherein upon said delivering step said hair cell is generated.

Claim 45. The method of claim 44 wherein said delivery vehicle is selected from the group consisting of an adenoviral vector, a retroviral vector, an adeno-associated viral vector, a plasmid, and a liposome[, a lipid, and a combination thereof].

Claim 112. A composition comprising an atonal-associated nucleic acid sequence in combination with a delivery vehicle, wherein said delivery vehicle results in delivery of a therapeutically effective amount of atonal-associated nucleic acid sequence into a cell, and wherein said atonal-associated nucleic acid sequence encodes a polypeptide that has inner ear

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hair cell generating activity, has at least about 80% identity to SEQ ID NO:58, and comprises at least about 80% identity to SEQ ID NO:70.

Claim 114. The composition of claim 113, wherein said vector is selected from the group consisting of a viral vector, and a plasmid vector[, or a combination thereof].

Claim 124. The composition of claim 112, wherein said delivery vehicle is a liposome[, a lipid, or a combination thereof].

During the telephone interview conducted on 2/20/04, Applicant's representative objected to the rejection raised with regard to claims drawn to method and composition that utilizes "lipid" or "combination thereof" for all the vectors as delivery vehicle. However, for the sole purpose of furthering prosecution, Applicants agreed to remove such recitation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine Qian, Ph.D.

Anne-Marie Falk
ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER